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REVIEW

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Early and late clinical outcomes and cost-effectiveness of aortic valve replacement using the Inspiris Resilia bioprosthesis

A systematic review and meta-analysis

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Abstract

Background The present study aimed to critically revise the published literature on clinical outcomes and cost-effectiveness of Inspiris Resilia valve.

Methods This work was conducted according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines. Full text research articles discussing clinical or cost-effectiveness aspects of Inspiris Resilia bioprosthesis published in English were included in this analysis. Studies were excluded if they weren't exclusively conducted on patients submitted to surgical aortic valve replacement using the Inspiris Resilia bioprosthesis.

Results The technical success rate was almost perfect in all studies. Reported complications included severe prosthesis-patient mismatch, reoperation, endocarditis, and paravalvular leak. In almost all studies, there were significant improvement of NYHA at the end of follow up as compared to baseline. In all studies, there were significant improvement of one or more hemodynamic parameters at the end of follow up as compared to baseline.

Conclusions Surgical aortic valve replacement using Inspiris Resilia tissue valve appears to be safe and effective with low rate of aortic valve and systemic complications and mortality. Its performance appears to be equal to or better than many other bioprosthetic valves. As compared to mechanical valves, its use is suggested to be more cost-effective.

Keywords Aortic valve, Aortic valve replacement, Bioprosthesis, Inspiris Resilia valve

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Introduction

Aortic valve disease (AVD) is the third common cause of cardiovascular disease with significant impact on patients' quality of life and survival. Surgical aortic valve replacement (SAVR) has been widely regarded as a reliable and safe technique. It remains the standard of care for AVD management [1]. Over the last two decades, minimally invasive aortic valve replacement has increasingly gained solid grounding as a safe and effective treatment modality in comparison to open and transcatheter approaches [2].

The choice between mechanical and bioprosthetic valves usually respects the current American College of Cardiology/American Heart Association (AHA/ACC) and European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/ EACTS) guidelines that recommend which type of aortic valve prosthesis should be used according to different clinical and surgical criteria [3, 4]. Use of mechanical valves is hampered by the need for lifelong anticoagulation therapy with its related side effects especially in younger patients. In contrast, biological valves are disadvantaged by the shorter durability attributed to the high risk of structural valve deterioration (SVD) and subsequent need for reoperation [5–7]. SVD is attributed to valve calcification and destruction of connective tissue caused by mechanical stress, lipid and inflammatory cells infiltration and immune system activation [8].

Many attempts have been done to improve the durability of biological valves with many innovations and technologies developed to achieve this target [9, 10]. The Carpentier-Edwards Perimount Magna Ease valve is a third-generation bioprosthesis used for SAVR with satisfactory safety profile and sustained hemodynamic and functional performance at the long-term [11]. More recently, a new generation bioprosthetic valve -the Inspiris Resilia- was introduced and approved for use in many countries across Europe, North America and Asia. Inspiris Resilia (Model 11000, Edwards Lifesciences, LLC) is made of tri-leaflet bovine pericardial tissue mounted underneath a flexible frame. It was built upon the Carpentier-Edwards Perimount Magna Ease valve design. It is characterized by three magnificent features: First, the valve tissue is biologically selected to reduce calcium deposition via blockade of aldehyde groups and thus increasing durability. Second, the stent frame is supplemented with as expansion feature (V-Fit) that facilitates further valve-in-valve procedures particularly in patients with small annuli. The frame is designed to be compliant at the orifice as well as at the commissures. The wire form is made from cobalt–chromium alloy to improve spring efficiency and fatigue-resistance. Third, glycerolisation treatment inhibits oxidation of the valve tissue which preserves the structural integrity of the collagen matrix during non-liquid storage [12].

Preclinical [13, 14] and early clinical [12] studies showed adequate safety profile and good clinical performance. Subsequently, multiple clinical trials and registries were initiated to assess the long-term outcome of the newly introduced technology including the COMMENCE trial [15], the RESILIENCE trial [16], the INDURE registry [17] and the IMPACT registry [18].

The present work aimed to critically revise the published literature on clinical outcomes and cost-effectiveness of Inspiris Resilia valve.

Methods

The present study was conducted according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines.

Inclusion and exclusion criteria

Full text research articles discussing clinical or cost-effectiveness aspects of Inspiris Resilia bioprosthesis published in English were included in this analysis. Studies were excluded if they weren't exclusively conducted on patients submitted to SAVR using Inspiris Resilia bioprosthesis.

Search strategy

Three biomedical databases were searched: Pubmed, Scopus and Web of Science Core Collection. Used keywords included aortic valve, aortic valve replacement, bioprosthetic aortic valve replacement and Inspiris Resilia aortic valve. Multiple word combinations were made using the Boolean operators AND/OR to maximize the search results. Search settings were adjusted to retrieve journal articles published in English up to May 1, 2024.

Collected data

Data collected from the cohort studies included baseline data (type of study, number of patients, age, sex distribution, surgical risk scores, and left ventricular ejection fraction), aortic valve pathology (bicuspid aortic valve, aortic stenosis, aortic regurgitation, aortic prosthetic dysfunction), operative parameters (valve size, surgical access, number of patients with isolated aortic valve replacement), early and late aortic valve outcome (technical success, severe patient-prosthesis mismatch (PPM), reoperation for valve replacement, valve endocarditis, valve explanation, valve thrombosis, structural valve deterioration, non- structural valve deterioration, significant paravalvular leak: > 2+), early and late systemic complications (arrhythmia, use of permanent pacemaker, thromboembolic complications, bleeding requiring surgical revision, hemolysis), mortality (all-cause and valve-related), functional performance (NYHA) at baseline and

at the end of follow up and hemodynamic parameters at baseline and the end of follow up.

Risk of bias assessment

Risk of bias in comparative studies included in the meta-analysis component was assessed using the ROBINS-I (Risk Of Bias In Non-randomised Studies - of Interventions) tool. This tool evaluated bias in non-randomized studies regarding 7 domains (bias due to confounding, bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes and bias in selection of the reported result) with overall risk of bias judgement [19].

Statistical analysis

Data were presented as number, mean and standard deviation or median and interquartile range. Meta-analysis of comparative studies was performed using Review Manager 5.4.1 (Cochrane Collaboration, UK). Studies included in meta-analysis were tested for heterogeneity of the estimates using Cochran's Q chi square test and I-square (I2) index. Binary outcomes across included studies were calculated using the Mantel-Haenszel methods and were expressed as log odds ratio with 95% confidence limits (95% CI). P-value < 0.05 was considered statistically significant.

Results

Search results

Search of the three databases identified 240 records which were reduced to 144 records after removal of duplicates. Screening of titles and abstracts resulted in exclusion of 116 records. Among the 28 full-text articles assessed for eligibility, 5 articles were excluded because they didn't exclusively study the Inspiris Resilia valve. The remainder 23 studies were systemically revised and 5 comparative studies were advanced to further meta-analysis to compare the overall prevalence of early thromboembolic events and all-cause mortality between Inspiris Resilia valve and other bioprosthetic valves (Fig. 1).

Risk of bias in studies included in meta-analysis

Using the ROBINS-I tool, studies included in meta-analysis for early thromboembolic events and mortality were judged to have low risk of bias.

Clinical findings in the included cohort studies

1. Overview of included cohort studies.

In this section, 18 studies are included. The study of Sadowski et al. [12] is the first clinical study to assess the Inspiris Resilia performance. The same group published more three articles with more patients and/or longer follow up duration [20–22]. The studies of El-Sayed Ahmad et al. [18] and El-Sayed Ahmad et al. [23] respectively described the one-year and mid-term outcomes of patients from the IMPACT trial. The studies of Puskas et al. [24], Johnston et al. [25], and Beaver et al. [26]. respectively reported two-year, mid-term and seven-year outcomes from the Commence trial. Other studies are listed in Table 1. The follow up duration in the included studies ranged from time to hospital discharge [27] to 5.3 ± 2.2 years [26]. Trial/Registry/Setting, country of origin, number of included centers and number of included patients are shown in Table 1.

2. Baseline data in the included cohort studies.

Among the included studies, there were 10 prospective and 8 retrospective studies. Number of included patients ranged from 20 [12] to 689 [24–26]. Patients' age ranged from 53.5 ± 6.9 years [28] to 75.1 ± 4.5 years [29]. Sex distribution of included patients, EuroSCORE, Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score and left ventricular ejection fraction (LVEF) are shown in Table 2.

3. Aortic valve pathology in the included cohort studies.

Presence of bicuspid aortic valve (BAV) and the prevalence of pure or combined aortic stenosis (AS) and regurgitation (AR) are shown in Table 3.

4. Operative data in the included studies.

Valve size 21 was the most commonly used valve size by 5 studies while valve size 23 was the most commonly used size by 11 studies. The most commonly or only used surgical access was full sternotomy in 12 studies while right anterior mini-thoracotomy (RAMT) was the main or only surgical access used in two studies (Table 4).

5. Early and late aortic valve outcome in the included cohort studies.

Six studies didn't report the technical success rate. The technical success rate was almost perfect in other studies. Reported complications included severe PPM, reoperation, endocarditis, and PVL (Tables 5 and 6).

6. Early and late systemic complications and mortality in the included cohort studies.

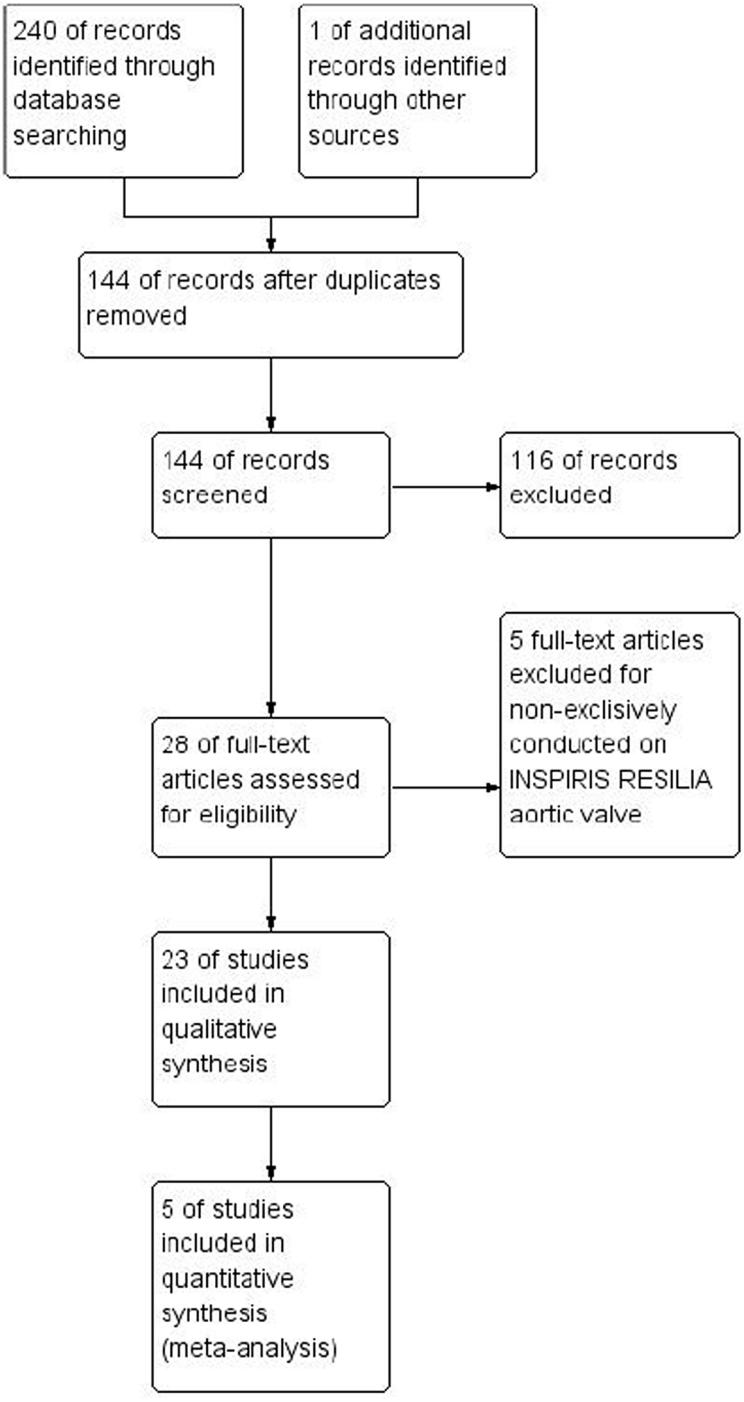

Fig. 1 Flow chart of search strategy

Reported systemic complications included arrhythmia which sometimes required permanent pacemaker implantation, thromboembolic complications, major bleeding and mortality including valve-related mortality (Tables 7 and 8).

7. Functional performance (NYHA) at baseline and at the end of follow up in the included cohort studies.

In all studies, there were significant improvement of NYHA at the end of follow up as compared to baseline (Table 9).

8. Hemodynamic parameters at baseline and the end of follow up in the included cohort studies.

Table 1 Included cohort studies ($n=18$)

Trial/registry/setting	Country	Centers *n*	Related studies	Patients *N*	Follow up
NCT01651052	Poland	1	Sadowski 2015 [12]	20	1 year
		2	Bartus 2018 [20]	133	1 year
			Bartus 2019 [21]		3.8 ± 1.1 years
			Bartus 2021 [22]		4.2 ± 1.5 years
COMMENCE trial (NCT01757665)	Multinational	27	Puskas 2017 [24]	689	1.2 ± 0.7 years
			Johnston 2021 [25]		3.7 ± 1.2 years
			Beaver 2023 [26]		5.3 ± 2.2 years
IMPACT trial (NCT04053088)	Germany	1	El-Sayed Ahmad 2021 [18]	100	1 year
			El-Sayed Ahmad 2022 [23]	154	2.05 ± 0.77 years
Quebec Heart and Lung Institute	Canada	1	Bernard 2023 [32]	488	18.0 (9.0–25.0) * months
Gemelli University Polyclinic Foundation/Poliambulanza Foundation	Italy	2	Chiariello 2023 [35]	74	2.4 (1.5–2.7) * years
Verona Medical School	Italy	1	Francica 2023 [40]	192	Up to 3 years
Hyogo Prefectural Amagasaki General Medical Center	Japan	1	Fukunaga 2022 [29]	29	19.2 ± 7.2 months
ACTIVIST registry	Japan	5	Maeda 2023 [34]	66	640 days
INDURE Registry (NCT03666741)	International	21	Meuris 2023 [28]	421	1 year
La Timone Hospital	France	1	Porto 2023 [41]	487	1 year
University Hospital Lausanne	Switzerland	1	Shala 2022 [31]	59	30 days
Ruhr-University Hospital Bergmannsheil	Germany	1	Useini 2021 [27]	80	Discharge (7.0 ± 2.0 days)

Data expressed as number (n), mean and standard deviation, median and interquartile range (*)

Table 2 Baseline data in the included cohort studies ($n=18$)

	Type of study	Patients *n* *	Age years	M/F *n*	Surgical risk scores		LVEF %
					EuroSCORE %	STS-PROM score %	
Sadowski 2015 [12]	Prospective	20	73.7 ± 4.8	7/13	NA	NA	NA
Bartus 2018 [20]	Prospective	133	65.3 ± 13.5	65/68	NA	NA	61.2 ± 13.7
Bartus 2019 [21]					NA	NA	
Bartus 2021 [22]					1.4 ± 1.0	1.4 ± 0.9	
Puskas 2017 [24]	Prospective	689	67.0 ± 11.6	495/194	2.5 ± 2.8	2.0 ± 1.8	NA
Johnston 2021 [25]							
Beaver 2023 [26]							
El-Sayed Ahmad 2021 [18]	Retrospective	100	56.0 ± 9.0	61/39	5.8 ± 6.4	NA	NA
El-Sayed Ahmad 2022 [23]	Prospective	154	56.8 ± 9.9	99/55	3.4 ± 3.6	NA	54.2 ± 9.8
Bernard 2023 [32]	Retrospective	217	69.0 ± 7.0	159/58	1.9 (1.3–3.5) #	NA	56.2 ± 10.6
Chiariello 2023 [35]	Retrospective	74	57.0 (47.0–62.0) *	67/7	NA	3.5 (1.2–7.5) #	59.0 (54.0–65.0) #
Francica 2023 [40]	Retrospective	122	57.0 ± 9.1	91/31	2.7 ± 2.4	NA	56.4 ± 10.9
Fukunaga 2022 [29]	Retrospective	29	75.1 ± 4.5	10/19	NA	NA	62.9 ± 14.7
Maeda 2023 [34]	Retrospective	64	74.2 ± 7.7	32/32	NA	NA	64.7 ± 12.8
Meuris 2023 [28]	Prospective	421	53.5 ± 6.9	322/99	1.5 ± 1.6	1.06 ± 0.99	59.3 ± 10.1
Porto 2023 [41]	Prospective	487	58.2 ± 11.5	366/121	4.8 ± 7.9	NA	60.0 (50.0–65.0) #
Shala 2022 [33]	Retrospective	59	71.0 ± 7.0	44/15	2.34 ± 1.6	NA	NA
Useini 2021 [27]	Retrospective	80	60.6 ± 8.3	58/22	3.6 ± 2.4	2.9 ± 1.7	54.9 ± 11.1

*Number of patients with available outcome data

Data expressed as number (n), mean and standard deviation, median and interquartile range (#)

LVEF: Left ventricular ejection fraction, M/F: Male/Female, STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality

Table 3 Aortic valve pathology in the included cohort studies ($n=18$)

	N	BAV	AS	Pure AS	AR	Pure AR	AS + AR	Prosthetic dysfunction
Sadowski 2015 [12]	20	NA	20	NA	NA	-	NA	-
Bartus 2018 [20]	133	NA	108	52	81	25	56	-
Bartus 2019 [21]		NA	NA	NA	NA	NA	NA	NA
Bartus 2021 [22]		NA	108	NA	81	NA	NA	NA
Puskas 2017 [24]	673	NA	604	343	307	46	261	17
Johnston 2021 [25]								
Beaver 2023 [26]								
El-Sayed Ahmad 2021 [18]	100	NA	93	NA	5	NA	NA	-
El-Sayed Ahmad 2022 [23]	152	NA	119	60	92	33	59	-
Bernard 2023 [32]	217	NA	217	160	57	-	57	-
Chiariello 2023 [35]	74	30	46	28	46	28	18	-
Francica 2023 [40]	122	59	NA	NA	88	NA	NA	-
Fukunaga 2022 [29]	29	NA	29	NA	NA	NA	NA	-
Maeda 2023 [34]	64	14	64	16	48	-	48	-
Meuris 2023 [28]	421	308	294	142	92	73	205	-
Porto 2023 [41]	487	NA	487	152	335	-	335	-
Shala 2022 [33]	59	10	48	NA	11	NA	NA	-
Useini 2021 [27]	80	NA	69	NA	11	NA	NA	-

AS: Aortic Stenosis, AR: Aortic Regurgitation, AE: Aortic Endocarditis, BAV: Bicuspid Aortic Valve

Table 4 Operative data in the included cohort studies ($n=18$)

	N	Valve Size						Surgical access			Isolated AVR
		19	21	23	25	27	29	Full Sternotomy	Partial sternotomy	RAMT	
Sadowski 2015 [12]	20	-	8	9	2	1	-	15	5	-	19
Bartus 2018 [20]	133	12	46	41	24	10	-	117	16	-	114
Bartus 2019 [21]											
Bartus 2021 [22]											
Puskas 2017 [24]	689	22	131	214	202	100	20	568	106	15	407
Johnston 2021 [25]											
Beaver 2023 [26]											
El-Sayed Ahmad 2021 [18]	100	2	15	42	26	14	1	-	-	100	100
El-Sayed Ahmad 2022 [23]	154	2	16	53	52	27	4	50	13	91	NA
Bernard 2023 [32]	217	2	47	74	61	30	3	217	-	-	84
Chiariello 2023 [35]	74	16		53		4		58	16	-	43
Francica 2023 [41]	122	12	23	42	29	14	2	122	-	-	57
Fukunaga 2022 [29]	29	8	13	7	1	-	-	25	4	-	NA
Maeda 2023 [34]	64	15	27	14	7	-	-	NA	NA	NA	64
Meuris 2023 [28]	421	5	56	131	125	77	27	302	112	7	255
Porto 2023 [41]	487	13	65	170	125	84	30	487	-	-	277
Shala 2022 [33]	59	23 (25 – 23) #						NA	NA	NA	39
Useini 2021 [27]	80	-	15	26	23	16	-	31	49		45

AVR: Aortic Valve Replacement, RAMT: Right Anterior Mini-thoracotomy

In all studies, there were significant improvement of hemodynamic parameters at the end of follow up as compared to baseline (Table 10).

Inspiris Resilia performance after bicuspid aortic valve replacement

One study [30] compared the clinical outcomes of bicuspid and tricuspid SAVR using the Inspiris Resilia valve. The valve showed excellent outcomes at 5 years with no structural valve deterioration and very low rates of paravalvular (0.7%) and transvalvular regurgitation (2.9%).

Comparison between Inspiris Resilia and other bioprosthetic valves

Six studies compared the clinical outcomes between Inspiris Resilia valve and other bioprosthetic valves (Tables 11, 12, 13, 14, 15 and 16). Bartus et al. [31] noted significantly lower rate of structural valve deterioration (SVD) in Inspiris Resilia tissue-based SAVR as compared

Table 5 Early aortic valve outcome in the included cohort studies ($n=18$)

	N	Technical success	Complications							
			Severe PPM	Reoperation	Endocarditis	Explant	Thrombosis	SVD	NSVD	PVL
Sadowski 2015 [12]	20	20	NA	-	-	NA	-	-	NA	-
Bartus 2018 [20]	133	133	NA	-	-	-	-	-	-	1
Bartus 2019 [21]				-	-	-	-	-	-	1
Bartus 2021 [22]				-	-	-	-	-	-	-
Puskas 2017 [24]	689	689	NA	1	-	-	-	-	-	1
Johnston 2021 [25]				1	-	-	-	-	-	1
Beaver 2023 [26]				1	-	-	-	-	-	1
El-Sayed Ahmad 2021 [18]	100	100	NA	-	-	-	-	-	NA	-
El-Sayed Ahmad 2022 [23]	154	154	NA	-	-	NA	-	-	NA	-
Bernard 2023 [32]	217	NA	NA	-	NA	NA	NA	-	NA	NA
Chiariello 2023 [35]	74	71	-	-	5	-	-	-	NA	-
Francica 2023 [40]	122	NA	NA	-	NA	NA	NA	-	NA	-
Fukunaga 2022 [29]	29	NA	NA	-	-	-	-	-	NA	-
Maeda 2023 [34]	64	NA	3.9%	NA	NA	NA	NA	-	NA	NA
Meuris 2023 [28]	421	417	4	-	-	NA	-	-	NA	-
Porto 2023 [41]	487	NA	7	NA	-	NA	-	-	NA	-
Shala 2022 [33]	59	NA	NA	-	-	NA	NA	NA	NA	NA
Useini 2021 [27]	80	80	NA	-	-	-	-	-	NA	-

NSVD: Nonstructural Valve Deterioration, PPM: Prosthesis Patient Mismatch, PVL: Paravalvular Leak, SVD: Structural Valve Deterioration

Table 6 Late aortic valve complications in the included cohort studies ($n=16$)

	N	Severe PPM	Reoperation	Endocarditis	Explant	Thrombosis	SVD	NSVD	PVL
Sadowski 2015 [12]	20	NA	-	-	NA	-	-	NA	-
Bartus 2018 [20]	133	NA	1	1	1	1	-	-	-
Bartus 2019 [21]			1	1	1	1	-	1	-
Bartus 2021 [22]			1	1	1	1	-	1	-
Puskas 2017 [24]	689	NA	3	5	3	-	-	-	1
Johnston 2021 [25]			7	11	6	-	-	-	2
Beaver 2023 [26]			11	15	NA	2	2	1	2
El-Sayed Ahmad 2021 [18]	100	NA	-	-	-	-	-	NA	-
El-Sayed Ahmad 2022 [23]	154	NA	1	1	NA	-	-	NA	1
Bernard 2023 [32]	217	15%	-	NA	NA	NA	2*	NA	NA
Chiariello 2023 [35]	74	6	-	-	-	-	-	NA	-
Francica 2023 [40]	122	NA	-	NA	NA	NA	-	NA	-
Fukunaga 2022 [29]	29	NA	-	-	-	-	-	NA	-
Maeda 2023 [34]	64	-	NA	NA	NA	NA	-	NA	NA
Meuris 2023 [28]	421	NA	1	1	NA	4	-	NA	-
Porto 2023 [41]	487	6	6	10	NA	1	-	NA	3

*Moderate SVD requiring no intervention

NSVD: Nonstructural Valve Deterioration, PPM: Prosthesis Patient Mismatch, PVL: Paravalvular Leak, SVD: Structural Valve Deterioration

to other contemporary prothesis while Bernard et al. [32] found that use of Inspiris Resilia valve is associated with lower rate of cardiovascular readmissions. Also, Bernard et al. [32] and Shala et al. [33] identified lower mean transvalvular gradient at follow up in the Inspiris Resilia valve and the study of Maeda et al. [34] recognized that effective orifice area in the Inspiris Resilia group was significantly larger than those in the Magna group. They also noted that patient-prosthesis mismatch at discharge was significantly lower in the Inspiris Resilia group than in the Magna group. In contrast, the study of Chiariello et al. [35] reported that use of Avalus valve is associated with better left ventricular mass reduction. Individual studies and overall analysis showed comparable outcomes between Inspiris Resilia valve and other valves regarding thromboembolic events (Fig. 2) and all-cause mortality (Fig. 3).

Cost-effectiveness of Inspiris Resilia

Three studies [36–38] performed cost-effectiveness analysis of SAVR using Inspiris Resilia valve. In the study of Carapinha et al. [36], a budget impact analysis was

Table 7 Early systemic complications and mortality in the included cohort studies ($n=18$)

	N	Complications								Mortality	
		Arrhythmia	Pacemaker	Thromboembolic				Bleeding	Hemolysis	All-cause	Valve-related
				All	Stroke	TIA	MI				
Sadowski 2015 [12]	20	1*	1	-	-	-	-	-	-	1	1
Bartus 2018 [20]	133	NA	NA	3	2	1	-	6	-	3	-
Bartus 2019 [21]		NA	NA	3	NA	NA	NA	9	-	3	1
Bartus 2021 [22]		NA	NA	3	NA	NA	NA	9	-	3	1
Puskas 2017 [24]	689	NA	31	15	11	4	-	6	-	8	3
Johnston 2021 [25]		NA	33	16	11	NA	NA	5	-	8	3
Beaver 2023 [26]		NA	NA	NA	11	NA	NA	5	-	8	NA
El-Sayed Ahmad 2021 [18]	100	24	1	-	-	-	-	-	NA	-	-
El-Sayed Ahmad 2022 [23]	154	35	3	3	3	-	-	4	NA	3	-
Bernard 2023 [32]	217	76 #	NA	6	4		2	9	NA	6	NA
Chiariello 2023 [35]	74	NA	2	-	-	-	-	6	NA	1	-
Francica 2023 [40]	122	31 #	2	3	NA	NA	NA	2	NA	-	-
Fukunaga 2022 [29]	29	NA	-	-	-	-	-	1	NA	1	-
Maeda 2023 [34]	64	NA	-	NA	NA	NA	NA	NA	NA	1	NA
Meuris 2023 [28]	421	NA	16	7	3	NA	NA	18	NA	3	-
Porto 2023 [41]	487	NA	23	4	4	-	-	28	NA	8	-
Shala 2022 [33]	59	-	-	1	1	-	-	1	NA	-	-
Useini 2021 [27]	80	19 #	-	2	1	-	1	3	NA	2	-

MI: Myocardial Infarction, TIA: Transient Ischemic Attack

* Atrioventricular block III, # Atrial fibrillation

Table 8 Late systemic complications and mortality in the included cohort studies ($n=16$)

	N	Complications								Mortality	
		Arrhythmia	Pacemaker	Thromboembolic				Bleeding	Hemolysis	All-cause	Valve-related
				All	Stroke	TIA	MI				
Sadowski 2015 [12]	20	-	-	-	-	-	-	-	-	-	-
Bartus 2018 [20]	133	NA	NA	1	NA	NA	NA	-	-	6	-
Bartus 2019 [21]		NA	NA	1	NA	NA	NA	2	-	16	4
Bartus 2021 [22]		NA	NA	2	NA	NA	NA	2	-	18	4
Puskas 2017 [24]	689	NA	9	17	8	9	-	21	-	18	6
Johnston 2021 [25]		NA	20	37	24	NA	NA	29	-	54	11
Beaver 2023 [26]		NA	NA	NA	26	NA	NA	40	-	70	NA
El-Sayed Ahmad 2021 [18]	100	NA	NA	-	-	-	-	-	NA	-	-
El-Sayed Ahmad 2022 [23]	154	NA	NA	-	-	-	-	-	NA	4	-
Bernard 2023 [32]	217	NA	NA	NA	NA	NA	NA	NA	NA	7	NA
Chiariello 2023 [35]	74	NA	1	2	1	-	1	-	-	5	-
Francica 2023 [40]	122	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fukunaga 2022 [29]	29	NA	NA	-	-	-	-	NA	NA	1	-
Maeda 2023 [34]	64	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Meuris 2023 [28]	421	NA	3	5	-	NA	NA	-	NA	4	-
Porto 2023 [41]	487	NA	27	11	7	-	4	NA	NA	12	-

MI: Myocardial Infarction, TIA: Transient Ischemic Attack

performed to compare the Inspiris Resilia and mechanical valves in aortic stenosis (AS) patients > 65 years up to five years postoperative in Saudi Arabia. The authors concluded that Inspiris Resilia tissue valves are overall budget saving commencing in year 1 and savings gradually increase year-on-year when compared with mechanical valves. They further explained that the higher costs of the initial procedure, reoperation, and additional monitoring (echocardiogram tests and visits) associated with Inspiris Resilia tissue valves are counterbalanced by savings in warfarin use, disabling strokes, major bleeding, and anticoagulation complications [36].

In another study, Keuffel et al. [37] performed economic evaluation to quantify the expected long-run savings of bioprosthetic valves with RESILIA tissue relative to mechanical valves given 5-year clinical results

Table 9 Functional performance (NYHA) at baseline and at the end of follow up in the included cohort studies ($n=18$)

	N	Baseline				End of follow up			
		I	II	III	IV	I	II	III	IV
Sadowski 2015 [12]	20	4	10	6		Same or improved: 84.2%			
Bartus 2018 [20]	133	28	61	42	2	Same or improved: 95.1%			
Bartus 2019 [21]		28	61	43	1	Improved: 54.5%			
Bartus 2021 [22]		28	61	43	1	Same: 36.3%; Improved: 54.9%			
Puskas 2017 [24]	689	166	342	168	13	Same: 31.0%; Improved: 65.7%			
Johnston 2021 [25]		164	344	168	13	Improved: 63.0%			
Beaver 2023 [26]						93.4%		6.6%	
El-Sayed Ahmad 2021 [18]	100	61		39		NA			
El-Sayed Ahmad 2022 [23]	154	NA				134		3	
Bernard 2023 [32]	217	61		156		NA			
Chiariello 2023 [35]	74	18		56		60		14	
Francica 2023 [40]	122	47	35	30	10	NA			
Fukunaga 2022 [29]	29	24		5		NA			
Maeda 2023 [34]	64	52		12		NA			
Meuris 2023 [28]	421	21.9%	51.0%	25.7%	1.4%	82.0%	14.5%	3.3%	0.3%
Porto 2023 [41]	487	260		227		425		17	
Shala 2022 [33]	59	NA				NA			
Useini 2021 [27]	80	40		40		NA			

Table 10 Hemodynamic parameters at baseline and the end of follow up in the included cohort studies ($n=18$)

	N	EOA cm^2		Peak Gradient mmHg		Mean Gradient mmHg	
		Baseline	End of follow up	Baseline	End of follow up	Baseline	End of follow up
Sadowski 2015 [12]	20	1.0 ± 0.5	1.8 ± 0.5	NA	NA	54.8 ± 21.2	11.3 ± 3.4
Bartus 2018 [20]	133	1.0 ± 0.8	1.8 ± 0.6	NA	NA	49.4 ± 21.7	13.9 ± 6.1
Bartus 2019 [21]			1.6 ± 0.4	78.5 ± 32.9	26.0 ± 12.9		14.5 ± 7.4
Bartus 2021 [22]			1.4 ± 0.5	NA	NA		14.8 ± 7.6
Puskas 2017 [24]	689	NA	1.6 ± 0.5	NA	NA	NA	10.1 ± 4.3
Johnston 2021 [25]		NA	1.5 ± 0.5	64.8 ± 27.5	21.0 ± 10.4	33.0 ± 14.5	11.0 ± 5.6
Beaver 2023 [26]		NA	1.82 ± 0.57	NA	NA	NA	9.4 ± 4.5
El-Sayed Ahmad 2021 [18]	100	0.9 ± 0.4	1.8 ± 0.1	71.3 ± 22.1	22.1 ± 3.1	42.1 ± 14.0	11.5 ± 2.3
El-Sayed Ahmad 2022 [23]	154	0.9 ± 0.2	1.9 ± 0.4	76.5 ± 19.4	23.6 ± 7.7	46.1 ± 12.3	13.9 ± 5.9
Bernard 2023 [32]	217	NA	NA	NA	NA	40.5 ± 18.9	11.4 ± 3.6
Chiariello 2023 [35]	74	NA	1.5 (1.3–1.7)	NA	21 (16–26)	NA	12 (10–15)
Francica 2023 [40]	122	NA	NA	65.8 ± 28.2	22.7 ± 9.1	43.9 ± 17.1	12.6 ± 5.5
Fukunaga 2022 [29]	29	0.72 ± 0.26	1.67 ± 0.36	89.3 ± 34.9	22.1 ± 6.7	51.9 ± 18.4	11.2 ± 3.3
Maeda 2023 [34]	64	0.75 ± 0.20	1.69 ± 0.34	NA	NA	50.2 ± 17.2	10.7 ± 5.1
Meuris 2023 [28]	421	1.07 ± 0.76	1.9 ± 0.6	70.6 ± 33.3	12.5 ± 5.3	45.3 ± 21.5	12.6
Porto 2023 [41]	487	NA	NA	NA	NA	49 (43–55)	9 (7–12)
Shala 2022 [33]	59	NA	NA	NA	NA	NA	10 (11 – 7)
Useini 2021 [27]	80	NA	NA	78.6 ± 22.8	19 ± 7.2	46.7 ± 14.8	10.2 ± 4.1

EOA: Effective Orifice Area

and expected performance through year 15 using data of 10,000 American patients. They found that relative to mechanical SAVR, expected net savings after 5 years for one patient are $9,110 and in 15 years horizon are $20,744.

In addition, Malcolm et al. [38] from the United Kingdom developed a decision-analytic model to evaluate the potential cost-effectiveness of SAVR using Inspiris Resilia tissue versus mechanical valves. They found that SAVR using Inspiris Resilia valves is potentially associated with higher quality-adjusted life years and potential cost savings that were greatest for those aged 55–64 years.

Discussion

The present work critically analyzed the published research articles on SAVR using the Inspiris Resilia bioprosthetic valve. Like other bioprosthetic valves, the main target of Inspiris Resilia development is to increase

Table 11 Early aortic valve outcome in Inspiris Resilia versus other bioprosthesis in comparative studies ($n=5$)

	N	Technical success	Complications (*n*/%)							
			Severe PPM	Reoperation	Endocarditis	Explant	Thrombosis	SVD	NSVD	PVL
Bernard 2023 [32]										
Inspiris Resilia	217	NA	NA	-	NA	NA	NA	-	NA	NA
Magna Ease	217	NA	NA	-	NA	NA	NA	-	NA	NA
Chiariello 2023 [35]										
Inspiris Resilia	74	71	-	-	5	-	-	-	NA	-
Avalus	74	74	-	-	1	1	-	-	NA	-
Francica 2023 [40]										
Inspiris Resilia	122	NA	NA	-	NA	NA	NA	-	NA	-
Magna Ease	122	NA	NA	-	NA	NA	NA	-	NA	-
Maeda 2023 [34]										
Inspiris Resilia	64	NA	3.9%	NA	NA	NA	NA	-	NA	NA
Magna Ease	64	NA	1.8%	NA	NA	NA	NA	-	NA	NA
Shala 2022 [33]										
Inspiris Resilia	59	NA	NA	-	-	NA	NA	NA	NA	NA
Magna Ease	66	NA	NA	-	-	NA	NA	NA	NA	NA

NSVD: Nonstructural Valve Deterioration, PPM: Prosthesis Patient Mismatch, PVL: Paravalvular Leak, SVD: Structural Valve Deterioration

Table 12 Late aortic valve complications in Inspiris Resilia versus other bioprosthesis in comparative studies ($n=5$)

	N	Severe PPM	Reoperation	Endocarditis	Explant	Thrombosis	SVD	NSVD	PVL
Bartus 2023 [31]									
Full cohorts									
Inspiris Resilia	689	NA	NA	NA	NA	NA	1.8%	NA	NA
Multiple *	936	NA	NA	NA	NA	NA	3.5%	NA	NA
Matched cohorts									
Inspiris Resilia	409	NA	NA	NA	NA	NA	1.0%	NA	NA
Multiple *	380	NA	NA	NA	NA	NA	4.8%	NA	NA
Bernard 2023 [32]									
Inspiris Resilia	217	15%	-	NA	NA	NA	2*	NA	NA
Magna Ease	217	16%	3	NA	NA	NA	-	NA	NA
Chiariello 2023 [35]									
Inspiris Resilia	74	6	-	-	-	-	-	NA	-
Avalus	74	4	2	3	-	-	-	NA	-
Francica 2023 [40]									
Inspiris Resilia	122	NA	-	NA	NA	NA	-	NA	-
Magna Ease	122	NA	4	NA	NA	NA	4	NA	-
Maeda 2023 [34]									
Inspiris Resilia	64	-	NA	NA	NA	NA	-	NA	NA
Magna Ease	64	-	NA	NA	NA	NA	-	NA	NA

*Carpentier–Edwards PERIMOUNT Magna Ease, Carpentier–Edwards PERIMOUNT Magna, Carpentier–Edwards PERIMOUNT, Carpentier–Edwards PERIMOUNT Theon, Other Carpentier–Edwards PERIMOUNT, Mitroflow, Trifecta/Trifecta GT, Mosaic, and other or unknown

NSVD: Nonstructural Valve Deterioration, PPM: Prosthesis Patient Mismatch, PVL: Paravalvular Leak, SVD: Structural Valve Deterioration

valve durability and minimize SVD observed in similar valves. Apparently, Inspiris Resilia valve can be regarded as a promising option in this aspect not only due to the low rates of SVD noted by different studies but also due the evidence shown by a long-term and large sample size comparative study of Bartus et al. [31] In their study, the authors compared SVD between full and matched cohorts from the COMMENCE and PARTNER 2 A trials. The COMMENCE trial used the RESILIA valve for SAVR while other non-Resilia valves were used in the PARTNER 2 A. At 5 years, the rates of SVD were 1.8 versus 3.5% in full cohorts and 1.0% and 4.8% in the matched cohorts in the COMMENCE and PARTNER 2 A trials respectively. Considering the fact that most patients in the PARTNER 2 A trial were managed using various versions of Carpentier–Edwards PERIMOUNT that lack the Inspiris Resilia tissue. Findings of that study support the suggestion that the Inspiris Resilia valve may provide better performance than other valves even in longer follow up duration.

Table 13 Early systemic complications and mortality in Inspiris Resilia versus other bioprosthesis in comparative studies ($n=5$)

	N	Complications								Mortality	
		Arrhythmia	Pacemaker	Thromboembolic				Bleeding	Hemolysis	All-cause	Valve-related
				All	Stroke	TIA	MI				
Bernard 2023 [32]											
Inspiris Resilia	217	76	NA	6	4		2	9	NA	6	NA
Magna Ease	217	87	NA	7	5		2	15	NA	5	NA
Chiariello 2023 [35]											
Inspiris Resilia	74	NA	2	-	-	-	-	6	NA	1	-
Avalus	74	NA	4	-	-	-	-	2	NA	2	1
Francica 2023 [40]											
Inspiris Resilia	122	31 #	2	3	NA	NA	NA	2	NA	-	-
Magna Ease	122	28	4	2	NA	NA	NA	5	NA	-	-
Maeda 2023 [34]											
Inspiris Resilia	64	NA	-	NA	NA	NA	NA	NA	NA	1	NA
Magna Ease	64	NA	4	NA	NA	NA	NA	NA	NA	-	-
Shala 2022 [33]											
Inspiris Resilia	59	-	-	1	1	-	-	1	NA	-	-
Magna Ease	66	-	-	1	1	-	-	1	NA	1	1

MI: Myocardial Infarction, TIA: Transient Ischemic Attack

Table 14 Late systemic complications and mortality in Inspiris Resilia versus other bioprosthesis in comparative studies ($n=4$)

	N	Complications								Mortality	
		Arrhythmia	Pacemaker	Thromboembolic				Bleeding	Hemolysis	All-cause	Valve-related
				All	Stroke	TIA	MI				
Bernard 2023 [32]											
Inspiris Resilia	217	NA	NA	NA	NA	NA	NA	NA	NA	7	NA
Magna Ease	217	NA	NA	NA	NA	NA	NA	NA	NA	15	NA
Chiariello 2023 [35]											
Inspiris Resilia	74	NA	1	2	1	-	1	-	NA	5	-
Avalus	74	NA	2	1	1	-	-	-	NA	3	3
Francica 2023 [40]											
Inspiris Resilia	122	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Magna Ease	122	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maeda 2023 [34]											
Inspiris Resilia	64	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Magna Ease	64	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

MI: Myocardial Infarction, TIA: Transient Ischemic Attack

Probably, one of the most debatable issues in SAVR using Inspiris Resilia valve is the appropriate selection of the suitable candidates. In fact, selection of suitable candidates for the procedure remains undetermined as shown by the wide variation of the inclusion and exclusion criteria in the analyzed studies and the baseline clinical and surgical characteristics of the included patients. For example, in El-Sayed Ahmad et al. [18] study, pregnancy was the only exclusion criteria and valve selection was based on many criteria such as lifestyle choice, desire for pregnancy, and/or contraindication for anticoagulation therapy while in another study by the same authors, patients with endocarditis and redo SAVR were excluded [22].

These criteria contradict the stricter conditions required by earlier studies. As expected, the initial clinical study of Sadowski et al. [12] restricted patients' eligibility to those with aortic valve disease requiring isolated replacement and excluded many patients including those with low LVEF, active endocarditis; concomitant valve disease and recent history of myocardial infarction.

Technically, SAVR using Inspiris Resilia tissue was mainly performed using full sternotomy surgical access. However, minimally invasive approaches were safely and effectively used in some studies. Like other aortic valve surgeries, the outcome of minimally invasive aortic valve replacement using Inspiris Resilia can benefit from additional technological advances e.g. video-assisted thoracoscopic surgery which can result in better procedural safety and performance, shorter cross-clamping and CBP time and shorter ICU and hospital stay as suggested by the study of El-sayed Ahmad et al. [18]

Table 15 Functional performance at the end of follow up in Inspiris Resilia versus other bioprosthesis in comparative studies ($n=5$)

	N	Follow up			
		I	II	III	IV
Bernard 2023 [32]					
Inspiris Resilia	217	NA	NA	NA	NA
Magna Ease	217	NA	NA	NA	NA
Chiariello 2023 [35]					
Inspiris Resilia	73	60		13	
Avalus	72	64		8	
Francica 2023 [40]					
Inspiris Resilia	122	NA	NA	NA	NA
Comparator	122	NA	NA	NA	NA
Maeda 2023 [34]					
Inspiris Resilia	64	NA	NA	NA	NA
Comparator	64	NA	NA	NA	NA
Shala 2022[33]					
Inspiris Resilia	59	NA	NA	NA	NA
Comparator	66	NA	NA	NA	NA

Table 16 Hemodynamic parameters at the end of follow up in Inspiris Resilia versus other bioprosthesis in comparative studies ($n=5$)

	N	EOA cm^2	Peak Gradient mmHg	Mean Gradient mmHg
Bernard 2023 [32]				
Inspiris Resilia	25	NA	NA	11.4 ± 3.6
Magna Ease	25	NA	NA	17.3 ± 6.6
Chiariello 2023 [35]				
Inspiris Resilia	73	1.5 (1.3–1.7)	21 (16–26)	12 (10–15)
Avalus	72	1.4 (1.2–1.5)	23 (15–28)	13 (8–17)
Francica 2023 [40]				
Inspiris Resilia		NA	22.7 ± 9.1	12.6 ± 5.5
Magna Ease		NA	22.8 ± 14.2	12.5 ± 8.8
Maeda 2023 [34]				
Inspiris Resilia	64	1.69 ± 0.34	NA	10.7 ± 5.1
Magna Ease	64	1.51 ± 0.30	NA	9.7 ± 4.5
Shala 2022 [33]				
Inspiris Resilia	48	NA	NA	9 [11 – 7]
Magna Ease	56	NA	NA	12 [15 – 9]

EOA: Effective Orifice Area

It has been also shown that use of Inspiris Resilia was associated with very low frequency of early and late aortic valve and systemic complications. The main reported complications included patient-prosthesis mismatch, reoperation for valve replacement, valve endocarditis, valve thrombosis, significant paravalvular leakage, arrhythmia, use of permanent pacemaker, thromboembolic complications and bleeding requiring surgical revision. Moreover, there was significant improvement of the functional performance as expressed by the NYHA classification and hemodynamic performance.

In a sub-analysis of the COMMENCE trial, it was shown that patients with bicuspid aortic valve had excellent 5-year safety outcomes after SAVR using the Inspiris Resilia valve with outcomes similar to patients with tricuspid aortic valve indicating that valve morphology is minimally related to the outcome of SAVR using the Inspiris Resilia. In fact, it was reported that bicuspid aortic valve may be associated with higher rates of PVL because of the asymmetrical annulus [39].

Comparison between the Inspiris Resilia valve and other bioprosthetic valves showed variable results. In one study comparing Inspiris Resilia and Magna Ease valves, no significant difference in short-term outcomes was observed, survival was similar at 30 months, but freedom from readmission was higher in the Inspiris Resilia group. Moreover, it was found that Inspiris Resilia valves had a lower mean gradient at discharge, 1–3 months and 24 months [31]. In another study, Maeda et al. [34] demonstrated that peak velocity and mean pressure gradient in the Inspiris Resilia group were comparable, while the effective orifice area in the Inspiris group was significantly larger than those in the Magna group. A patient-prosthesis mismatch at discharge was significantly lower in the Inspiris Resilia group than in the Magna group. Also, it was shown that Inspiris Resilia group tended to have lower trans-prosthetic pressure gradients, reduced trans-prosthetic blood flow acceleration and increased permeability indices as compared to the Magna Ease group [33]. In another study, however, early and late outcomes were found to be comparable between the Inspiris Resilia and Avlus valves regarding valve-related mortality,

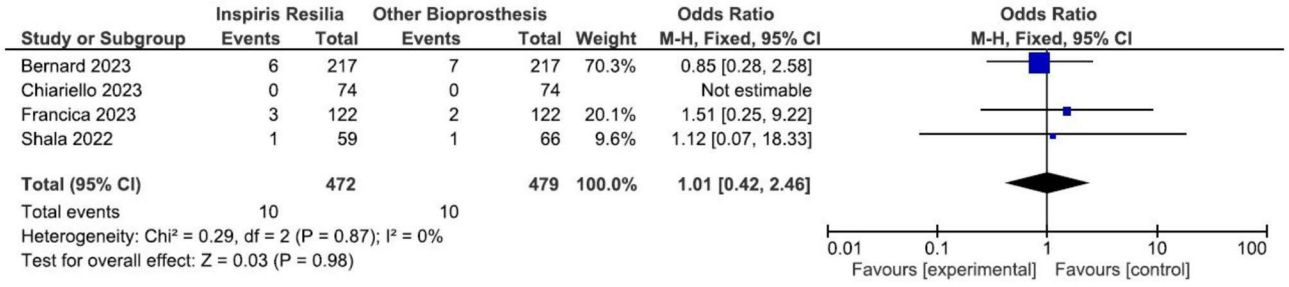

Fig. 2 Thromboembolic events in Inspiris Resilia and other bioprosthetic valves

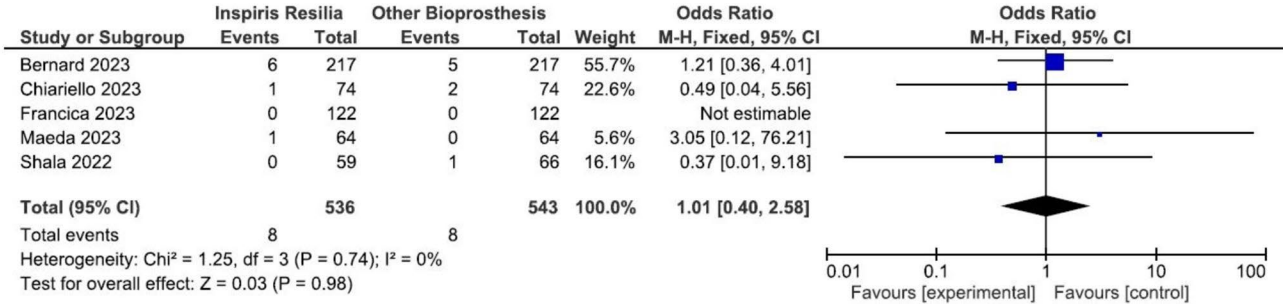

Fig. 3 All-cause mortality in Inspiris Resilia and other bioprosthetic valves

prosthetic endocarditis, reoperation, SVD or significant paravalvular leak [35]. Similar conclusions were reported by the study of Francica et al. [40] which compared Perimount Magna Ease and Inspiris Resilia Valve.

In respect to the cost-effectiveness, findings of studies suggested that Inspiris Resilia tissue valves proved to be cost-effective as compared to versus mechanical valves [36–38]. While these studies acknowledged the fact that SAVR using Inspiris Resilia is initially more expensive, they explained that other long-term costs related to mechanical valves including warfarin use, disabling strokes, major bleeding, and anticoagulation complications are much more costly.

Conclusions

In conclusion, SAVR using Inspiris Resilia tissue valve appears to be safe and effective with low rate of aortic valve and systemic complications and mortality. As compared to mechanical valves, its use is suggested to be more cost-effective.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13019-024-03269-7.

Supplementary Material 1

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Author contributions
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Data availability
No datasets were generated or analysed during the current study.

Declarations

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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